

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

-----	X	
MEDA AB,	:	
	:	
Plaintiff,	:	
	:	
v.	:	No. 11 Civ. 0412 (AJN)
	:	
3M COMPANY, 3M INNOVATIVE	:	
PROPERTIES COMPANY, and RIKER	:	
LABORATORIES, INC.,	:	
	:	
Defendants.	:	
-----	X	

DEFENDANTS' POST-TRIAL MEMORANDUM OF LAW

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Defendants 3M Company, 3M Innovative Properties Company, and Riker Laboratories, Inc. (collectively, “3M” or “Defendants”) hereby submit their Post-Trial Memorandum of Law:

A. Meda’s Breach Of Contract Claim Is Without Merit.

1. The French Agreement between 3M Santé and Meda France, dated January 1, 2007 (DX-330), was the operative contract with regard to the sale of the “assets, properties, and rights (the ‘Assets’)” attached to “the business (the ‘Business’) in France of developing, marketing, detailing and selling prescription and over-the-counter drug products” – including Tambocor CR.¹ That Agreement, to which Meda and 3M were also bound, expressly “supersede[d] all prior agreements and understandings, both written and oral” with respect to the subject matter thereof. *See* DX-330 at § 7.9.² Nevertheless, even if the Court ultimately holds that the representations and warranties set forth in the prior Acquisition Agreement, dated November 8, 2006, survived the subsequent negotiation and execution of the French Agreement and the Closing of the sale of the French Business and Assets – or finds that the French

¹ *See* Defendants’ Pretrial Memorandum of Law (#130) at 1 and 5-12; Defendants’ Response to Plaintiff’s Pretrial Memorandum of Law (#172) at 28-29; Defendants’ Reply Memorandum of Law in Support of Their Motion *in Limine* (#179) at 1-10; and Defendants’ Letter to the Court dated January 18, 2013, regarding the admissibility of evidence of the French Acquisition Agreement, at 1-6.

² The accompanying Side Letter among 3M, Meda, 3M Santé, and Meda France stated that “the French Agreement (in particular its provisions relating to the price’s adjustment and employee matters)” would be implemented “in accordance with the more detailed provisions contained in the [Acquisition] Agreement.” DX-336 at (i) (emphasis added). The phrase “in particular” is language of limitation, which means “specifically,” unless the context in which it appears is clearly to the contrary. *See* Abbott, *The WTO Medicines Decision, World Pharmaceutical Trade and the Protection of Public Health*, 99 Am. J. Int’l L. 317, 352 n.256 (2005); *see also* *United States v. Schramm*, 75 F.3d 156, 163 (3d Cir. 1996). Thus, only “the more detailed provisions” of the Acquisition Agreement “relating to the price’s adjustment and to the employee matters” were incorporated by reference into the French Agreement – and that was only in the event that there was a conflict between the two documents with respect to those matters. *See* DX-336 at (i) and (ii).

Agreement and accompanying Side Letter (DX-336) are ambiguous in that regard³ – Meda has not fulfilled its burden of proving any breach of contract by Defendants.

2. Meda alleges that Defendants – by not including an *entire class* of reimbursement pricing agreements (including certain documents containing Article 2.2) in the due diligence materials made available to Meda and by not disclosing 3M Santé’s purported violation of Article 2.2⁴ – breached three sections of the “Representations and Warranties” in the parties’ Acquisition Agreement: (1) Section 3.07 (entitled “Compliance with Laws”); (2) Section 3.12 (entitled “Contracts”); and (3) Section 3.15 (entitled “Regulatory Matters”). *See* Amended Complaint at ¶¶ 7 and 67-84. As demonstrated herein, Meda’s breach of contract claim is without merit.⁵

1. Meda’s claim under Section 3.07 must be dismissed.

3. In Section 3.07 of the Acquisition Agreement, Defendants represented: (1) “[t]o Seller’s Knowledge, the Business is not in violation of any Law;” and (2) “[s]ince December 31, 2004, Seller has complied in all material respects with all applicable regulatory requirements and all industry guidance concerning the marketing, promotion and distribution of medicinal

³ That the French Agreement was intended to govern the purchase and sale of the French Assets and Business, and the post-Closing implementation of that transaction, is reflected by the fact that the French Agreement was twice amended *after* the Closing – effective on December 31, 2007 (DX-393), and September 20, 2008 (DX-421). In contrast, the only amendment to the previous Acquisition Agreement was on December 29, 2006 (DX-316), which was *prior* to the Closing and the French Agreement. *See also* Keel Trial Decl. at ¶¶ 74-75 and 78-79.

⁴ Specifically, Meda alleges that 3M was obligated to provide and/or disclose the Convention dated March 10, 2003, and the 2004 and 2005 Amendments to the Convention dated November 17, 2003 (JX-19; DX-42; and JX-42), which contained Article 2.2, as well as a letter sent by 3M Santé to CEPS dated September 8, 2006 (JX-93). *See* Amended Complaint at ¶¶ 70, 73, 79, and 84.

⁵ *See also* Defendants’ Post-Trial Fact Memorandum With Citations to Record Evidence, filed January 30, 2013 (“Def. Fact Mem.”), at §§ I.A.2. and II.

products in the Territory.” *See* DX-281 at 26-27. Meda contends that Defendants breached those provisions because 3M Santé allegedly violated Article 2.2. *See* Amended Complaint at ¶¶ 60-61. As demonstrated below, Meda’s arguments are without merit.

a. To “Seller’s Knowledge,” 3M’s European pharmaceutical “Business” was not in violation of any “Law.”

(1) The state of “Seller’s Knowledge”

4. The phrase “Seller’s Knowledge” is defined in the Acquisition Agreement to mean the “actual knowledge of any of the individuals without inquiry listed in Section 1.01(e) of the Seller Disclosure Schedule.” *See* DX-281 at 6, § 1.01. The only persons listed in Section 1.01(e) of the Seller Disclosure Statement relevant to this matter are Benoit Traineau, John Sampson, and Ton van’t Hullenaar. *See* DX-348, Seller Disclosure Schedule, at § 1.01(e) (3M00171493). None of those individuals believed, let alone had “actual knowledge,”⁶ that Article 2.2 required a 50% reduction (or any reduction) in the reimbursement price of Tambocor CR in April 2006. *See* Traineau Trial Decl. at ¶¶ 14-15; Tr. at 1169 (Traineau); Ton van’t Hullenaar Dep. at 111-12; Tr. at 838-46 (Sampson).

(2) Article 2.2 was eliminated in September 2006.

5. Article 2.2 of the Convention dated March 10, 2003 (the “March 2003 Convention”), ceased to exist when CEPS and 3M Santé entered into their subsequent Convention dated November 17, 2003. *See* PX-41; Schur Trial Decl. at ¶ 49; Tr. at 1357-58

⁶ The Court should reject Meda’s attempt to disregard the plain language of the definition of “Seller’s Knowledge” by asserting that 3M’s alleged “failure to investigate” the truth of Section 3.07 with respect to Article 2.2 is “sufficient to find 3M breached its warranty.” *See* Meda’s Post-Trial Conclusions of Law (“Meda’s COL”) at 3-4. Unlike the decision on which Meda relies (*State Street Trust Co. v. Ernst*, 278 N.Y. 104 (1938), which involved an accountant’s alleged liability for gross negligence and fraud in the absence of a contractual relationship), the Acquisition Agreement specifically conditioned certain of Seller’s representations with the qualifying phrase “actual knowledge” (*i.e.*, knowledge “without inquiry”). *See* DX-281 at 6, § 1.01.

(Schur).⁷ Although it was later added to Annex 4 to the Amendment dated September 10, 2004 (DX-42), and again included in the Annex 4 to the subsequent Amendment dated August 29, 2005 (JX-42 and JX-42A), Article 2.2 was finally eliminated by virtue of those parties' final Amendment, dated September 15, 2006. *See* JX-95 and JX-95A. *See also* Tr. at 1354-58 (Schur).

6. Circumstances in the latter half of 2006 necessitated new negotiations between CEPS and 3M Santé relating to the price of Tambocor CR because: (a) the social security reimbursement listings for Tambocor IR and CR were up for renewal on July 25, 2006 (Schur Trial Decl. at ¶¶ 61, 56(c), and 63; Tr. at 1341 (Schur)), which meant potential price changes (*see* DX-38 at 30); and (b) the convention dated November 17, 2003, as amended, was to expire on December 31, 2006 (*see* PX-41 at art. 4.1). Thus, in January 2006, prior to the expiration of the 3-year timeframe set forth in Article 2.2 (*see* Schur Trial Decl. at ¶ 86), 3M Santé initiated the negotiation process by filing with CEPS its "Request for Renewal of Registration on the List of Reimbursable Drugs," in which it requested "maintenance of the price of Flecaine LP at €17.10." *See* JX-49A at MEDA 177804; Tr. at 1310 (Schur). *See also* JX-50A; Traineau Trial Decl. at ¶ 27; Biffaud Trial Decl. at ¶ 45.

7. By letter to Mr. Renaudin dated September 8, 2006, Mr. Philippe Husson, CEO of 3M Santé: (a) delivered to CEPS a partially-executed Amendment to the Convention of November 17, 2003 (JX-95 and JX-95A); (b) advised CEPS that "this [amended] agreement contains a substantial change that we wish to make you aware of on the advice of Ms. Soheila Leger [an employee of CEPS, whose function was "Agreements Supervision – Medications," *see* JX-173B at 72], with whom my colleagues met [that] week;" and (c) referred to "the various

⁷ *See also* Defendants' Memorandum of Law in Opposition to Plaintiff's Motion *In Limine* Relating to Affirmative Defenses (#191) at 4-10.

meetings you held with myself and my colleagues during the year 2006 (the most recent being on July 19, 2006).” JX-93A. The “substantial change” to which 3M Santé referred was the handwritten striking-out of the Tambocor-related provisions (including Article 2.2) of the proposed Annex 4, each page of which was signed by Mr. Husson. *See* JX-95 at MEDA 175878-79. Mr. Renaudin, on behalf of CEPS, counter-signed the Convention Amendment on September 15, 2006. *See* JX-95 and JX-95A.⁸ By Mr. Renaudin’s execution of the Amendment dated September 15, 2006, CEPS agreed to eliminate Article 2.2⁹ and maintain the price of Tambocor CR at its pre-existing, 42 month-old level of €17.10. *See* JX-95 and JX-95A. A convention or amendment “leaving the prices of . . . proprietary medications unaltered at the levels fixed in [the prior] rider” must be regarded as a decision by CEPS against any “alteration of the price.” DX-93 (2005 *Pfizer* decision), at 6 of 7.

8. The Amendment dated September 15, 2006, to the Convention of November 17, 2003, was the operative agreement between CEPS and 3M Santé in effect both as of the

⁸ “The chairman [of CEPS] shall sign the agreements made and the decisions taken pursuant to,” among other statutory provisions, “articles L.162-16-4 . . . L.162-17-3, [and] L162-17-4” (DX-44, Art. D 162-2-5, at 4 of 5), and, thus, the chairman’s signature reflects that conventions and related decisions have been approved by CEPS and that CEPS is bound thereby. *See* Schur Trial Decl. at ¶ 87.

⁹ It was not necessary for Mr. Renaudin to initial the handwritten strike-out of the Tambocor-related provisions of Annex 4 to the Convention Amendment dated September 15, 2006. *See* Schur Trial Decl. at ¶ 88. Under French law, such initialing is only necessary in connection with formal, *e.g.*, notarized, instruments (*see* DX-1, Decree 71-941, at 11 of 20, art. 13), and the execution of conventions is not subject to notarial or comparable formalities. *See* Schur Trial Decl. at ¶ 88. Meda itself made handwritten changes to conventions and amendments proposed by CEPS that were not initialed by Mr. Renaudin, but which were nevertheless effective. *See* JX-115 and JX-126. *See also* Tr. 512-13 and 525-26 (Destal). With respect to handwritten corrections to instruments such as CEPS conventions, trial judges “must accept the text as it appears following the corrections,” unless the party making the handwritten changes “added some wording after the typed text of the document had been compiled and signed” by CEPS (*see* DX-440, French Evidence Treatise, at 8 of 10) – which was not the case here. *See* Husson Dep. at 40.

Acquisition Agreement dated November 8, 2006, and at the Closing on January 2, 2007. *See* Tr. at 1356-57 (Schur). Article 2.2 was eliminated by that Amendment and, therefore, did not exist (and could not have been violated) as of either of those two events. *See* Schur Trial Decl. at ¶¶ 87-92, 96. Meda is unable to muster a credible argument to the contrary.

(3) Article 2.2 did not constitute a “Law.”

9. Meda variably refers to Article 2.2 as a “regulation,” some “other requirement or rule enacted or promulgated by [a] Governmental Authority, including [a] Governmental Order,” and/or a “stipulation” entered “by or with a Governmental Authority.” Of course, as demonstrated above (*see supra* § A.1.a.(2)), Article 2.2 did not even exist as of the parties’ execution of the Acquisition Agreement and subsequent Closing – and, in any event, to “Seller’s Knowledge,” there was no violation of Article 2.2 as of either of those two events. *See supra* § A.1.a.(1). Furthermore, as demonstrated below, even during its existence, Article 2.2 imposed no regulatory or contractual obligation on Defendants or 3M Santé that was violated or breached – and, thus, was not a “Law” under any of the various definitions of that term.

b. “Seller” had complied with applicable regulatory requirements and industry guidance since December 31, 2004.

10. “Seller”¹⁰ was never in violation or breach of Article 2.2. In addition, as discussed below, Article 2.2 simply contemplated further negotiations toward a new agreement

¹⁰ As previously noted (Tr. at 74-75), the term “Seller” is defined in the Acquisition Agreement as 3M Company, 3M Innovative Properties Company, and Riker Laboratories, Inc., collectively (*i.e.*, Defendants in this action). *See* DX-281 at 1. In contrast, the term “Sellers” is defined as “Seller” and each “Subsidiary” thereof. *Id.* The distinction between “Seller” and “Sellers” (the latter of which includes Subsidiaries of “Seller”) is an important one. Some of the provisions of the representation and warranty sections in Article III of the Acquisition Agreement are limited to matters regarding the acts and conduct of “Seller” (such as the second sentence in Section 3.07), whereas other provisions relate more broadly to “Seller and its Subsidiaries” (such as Sections 3.08, 3.09(b), and 3.11(d)).

as to the future price of Tambocor CR – and, as demonstrated (*see supra* § A.1.a.(2)), 3M Santé appropriately initiated those negotiations and accomplished that objective.

(1) **Article 2.2 did not mandate a price change and, thus, did not constitute a “regulatory requirement.”**

11. A decision by CEPS “to fix the price of a reimbursable medication” is “a regulatory act,” whether “the business marketing the medication agrees to the price” or the price “is otherwise determined by an interministerial decree.” DX-37 (2004 *Servier* decision), at 7 of 9. *See also* DX-32 (2003 *Serono I* decision), at 9 of 11; Schur Trial Decl. at ¶¶ 28 and 30; Tr. at 1305-06, 1348-49 (Schur); DX-41. Article L 162-17-4 of the French Social Security Code contemplates the possible inclusion in conventions of provisions for “changes” to the current fixed prices of pharmaceutical products. *See* DX-31 at 5 of 8. *See also* DX-43 (2004 *Bayer* decision), at 6 of 7. However, in order for a provision of a convention to constitute an effective future price change clause, it must clearly and unambiguously specify the new price (expressed in a monetary amount or a percentage thereof) or set forth a precise formula for calculating such an amount. Schur Trial Decl. at ¶ 22(a) and (b). If future “changes in the sale price of a medication have been provided by the convention,” CEPS “shall make sure that the conditions for changes in the prices set by the convention have been met.” PX-564A, Art. R 162-20-1. If CEPS “considers the said conditions to have been met,” the “new price” is “published in the Official Journal before [the effective] date.” *Id.*¹¹ The pharmaceutical company cannot set a

¹¹ In connection with such price changes, the drug company need only provide CEPS with any “items of information” that are “necessary” to CEPS (*i.e.*, information that CEPS does not already have in its possession or is not otherwise available to it) at least 40 days prior to the effective date. *Id.* CEPS is aware whether and when any particular reimbursable proprietary or generic drug has been introduced to the market, as well as the identity of the pharmaceutical company marketing such products. Tr. at 1358-59 (Schur). If the occurrence or existence of any of those facts constitutes the operative condition to a price change, publication of a new price by CEPS is all that is required to effectuate that change. DX-105 (2005 *Serono II* decision) at 6 of 7. *See also* DX-56, Art. R 162-17-3, at 5 of 8; Schur Trial Decl. at ¶ 25; Tr. at 1327-28 (Schur).

new price itself. *See* Schur Trial Decl. at ¶¶ 25, 46, and 51; Tr. at 1340-1341 (Schur). On the other hand, a provision that merely contemplates future negotiations does not constitute a price change clause under Article L 162-17-4(1). Rather, such provisions are essentially agreements to agree. *See* Schur Trial Decl. at ¶ 22(c).

12. Pursuant to the March 2003 Convention, the price of Tambocor CR was set at €17.10. *See* JX-19 and JX-19A. That convention also contained Article 2.2, which provided: “The Laboratory agrees to take all necessary steps to ensure that, at the end of a 3-year period dating from the publication in the Official Journal of the prices of the proprietary drugs mentioned in Table 2 of Article 1 [relating to Tambocor CR], an equivalent of each of these proprietary drugs, or failing that, each of these proprietary drugs, are placed on the market at the price of the generic drug corresponding to these proprietary drugs.” *Id.* Although Meda repeatedly refers to Article 2.2 as the “French Flecaine Price Reduction Agreement” (Amended Complaint, *passim*),¹² Article 2.2 was not a future price change clause, as described above, because it did not clearly and unambiguously specify a new price (expressed in a monetary amount or as a percentage thereof) or set forth a precise formula for calculating such an amount. *See* Schur Trial Decl. at ¶¶ 45-47; Tr. at 1363 (Schur). Consequently, Article 2.2 was not a regulatory act. Tr. at 1348-49 (Schur). Contrary to Meda’s allegation that Article 2.2 required a 50% reduction in the price of Tambocor CR by April 12, 2006, the price of a “generic drug corresponding to” Tambocor CR was not fixed at 50% of the price of Tambocor CR. Schur Trial

¹² Meda admits that Article 2.2 was written in the disjunctive, and thereby contemplated alternative scenarios. *See* Amended Complaint at ¶ 7. Recognizing that CEPS and the French “national health authorities do not have legal powers to enforce [a] product’s release to market” (*see* DX-356, Ministerial Response, at 5 of 7; Tr. at 1338-39 (Schur); Schur Trial Decl. at ¶ 46(f)), and the absence of any statutory remedies for any matters other than drug pricing (*see* DX-41, Art. R 162-16-4, at 5 of 7), Meda focuses on the alleged (but, as demonstrated herein, nonexistent) price reduction clause purportedly set forth in the latter part of Article 2.2.

Decl. at ¶¶ 46(e) n.17, 50, and 53-54. In 2006, 50% was merely the *minimum* price that a generic manufacturer could obtain from CEPS in the event the manufacturer, for whatever reason, chose not to engage CEPS in negotiations for a higher price. *See* PX-417A at 15; Tr. at 1328-29 (Schur). A higher price (or lower percentage reduction from the price of the proprietary drug) could be negotiated with CEPS. *See* Tr. at 1350-51 (Schur); DX-112, Ministerial Response, at 5 of 7. Put simply, the 50% “floor” was not applicable to negotiated pricing – such as that envisioned by Article 2.2.

13. In sum, at no time in 2006, either prior to or after the Amendment dated September 15, did CEPS: (1) publish a “new price” for Tambocor CR; (2) inform 3M Santé that CEPS considered any “conditions” to any alleged price change provision to have been met; (3) assert that 3M Santé needed to provide it with any information “necessary” in order to effectuate any purported price change provision; or (4) suggest that 3M Santé was in breach or violation of Article 2.2. In fact, there was no such “breach” or “violation” (*see* Schur Trial Decl. at ¶¶ 48 and 85), because Article 2.2 did not establish a fixed price or set forth a precise formula for calculating a future price for either Tambocor CR or the hypothetical “generic drug corresponding to” Tambocor CR. *See* Tr. at 1351, 1353 (Schur).¹³ It could not, therefore, be effectuated by CEPS. *See* Tr. at 1352 (Schur); Schur Trial Decl. at ¶ 45. Article 2.2 contemplated further negotiations between CEPS and 3M Santé for the purpose of establishing the future price of Tambocor CR – regardless of whether it was to continue at €17.10 or change to some lesser amount. *See* Tr. at 1353 (Schur); DX-38 at 28; Schur Trial Decl. at ¶¶ 46(g) and

¹³ Meda’s alternative argument that Article 2.2 obligated 3M Sante to launch an “equivalent” of Tambocor CR, and that 3M Sante failed to do so, ignores the fact that Article 2.2 provided two options – one of which necessitated another negotiation with CEPS. *See supra* n. 12.

48. Accordingly, Article 2.2 was not a “stipulation”¹⁴ or “regulatory requirement;” at most, it was an “agreement to agree.” Schur Trial Decl. at ¶¶ 22(c), 24, and 47.

(2) Article 2.2 did not constitute “industry guidance.”

14. There is no evidence that Article 2.2 constituted “industry guidance.”¹⁵ Rather, the only proof in the record of the meaning of that term is Section 3.07 itself, which indicates that “industry guidance” refers to codes of practice or similar documents issued publicly to the pharmaceutical industry. *See* DX-281 at § 3.07.

(3) Between December 31 2004, and the Closing, 3M Santé complied in all material respects with Article 2.2.

15. Because Article 2.2 did not set a price or provide a price change formula, it was not a “regulatory requirement.” *See supra* § A.1.b.(1). Nor was it “industry guidance.” *See supra* § A.1.b.(2). Even in the unlikely event that the Court held otherwise, 3M Santé did what Article 2.2 contemplated – namely, it initiated a process that led to a new amendment and an agreement as to the future price of Tambocor CR. In sum, 3M Santé was not in violation of Article 2.2 at *any* point in time and, therefore, Meda failed to prove any breach by Defendants of Section 3.07 of the Acquisition Agreement.

¹⁴ A stipulation is contractual in nature. *See Black’s Law Dictionary*, 9th Ed., at 1550 (defining “stipulation” as “[a] material condition or requirement of an agreement”). Article 2.2 did not constitute a contractual obligation. *See* Schur Trial Decl. at ¶¶ 47 and 96.

¹⁵ Rather, Meda’s counsel simply argues that Article 2.2 was tantamount thereto because “CEPS [was] telling 3M what it wants the price to be” (*see* Tr. at 1391-95 and 36-37), and was “guidance of which only 3M was aware.” *See* Meda’s COL at 7. But such private, firm-specific communications do not constitute “industry guidance.” *See* 21 C.F.R. § 10.115(b) (“Guidance documents do not include: . . . warning letters, memoranda of understanding, or other communications directed to individual persons or firms.”); *In re Prograf Antitrust Litig.*, 2012 WL 293850, at *1 (D. Mass. Feb. 1, 2012) (“The FDA publishes documents called ‘Guidance for the Industry’ . . . to communicate to the public its current thinking on a subject . . .”).

2. Pursuant to Section 5.02(b) of the Acquisition Agreement, Defendants had no duty to provide the CEPS Conventions or Amendments to Meda.

16. Defendants had no contractual obligation to disclose or otherwise make available to Meda the March 2003 Convention and the 2004 and 2005 Amendments to the Convention dated November 17, 2003 (the “2004 and 2005 Amendments”) – even if Sections 3.12(a) and/or 3.15(b) could be construed as applying to those documents. The introductory paragraph to Article III of the Acquisition Agreement, entitled “Representations and Warranties of the Seller,” begins with the qualifying phrase: “Except as . . . specifically contemplated by this Agreement,” and then sets forth the enumerated warranties, including those on which Meda sues. DX-281 at 24. One of the important conditions to those warranties is Section 5.02(b), which provides, in pertinent part:

Notwithstanding anything contained in this or any other agreement between Purchaser and Seller executed on or prior to the date hereof, Seller shall not have any obligation to make available to Purchaser or its representatives, or provide Purchaser or its representatives with . . . (ii) any information if making such information available would . . . (y) contravene any applicable Law or binding agreement (including any confidentiality agreement to which Seller or any of its Affiliates is a party) . . .

DX-281 at 37. The CEPS Convention dated November 17, 2003 – which abrogated the March 2003 Convention (*see* Tr. at 1342 (Schur)) and is the document to which the 2004 and 2005 Convention Amendments relate (*see* DX-42; JX-42 and JX-42A) – contained such a “confidentiality” agreement. *See* PX-41 and PX-41A at Article 4.1 (“The parties reciprocally undertake to respect [this agreement’s] confidentiality.”); Tr. at 1342 (Schur). Thus, pursuant to Section 5.02(b), Defendants were not obligated to provide to Meda the March 2003 Convention or the 2004 and 2005 Amendments – and, therefore, did not breach Sections 3.12(a) or 3.15(b)

by excluding those documents from the due diligence materials.¹⁶

17. Meda ignores both the language and implications of Section 5.02(b) (which it erroneously refers to as “5.05(b)”) by arguing that “confidentiality was no bar to disclosing the Convention to Meda,” because “Meda was under a confidentiality agreement with 3M.” Of course, the confidentiality agreement between Defendants and Meda (which the Acquisition Agreement acknowledges, *see* DX-281 at § 5.02(a)) did not change the fact that 3M Santé was subject to a separate confidentiality agreement *with CEPS* pursuant to the Convention dated November 17, 2003, and the subsequent 2004, 2005, and 2006 Amendments thereto. *See supra* ¶ 16. Under Section 5.02(b) of the Acquisition Agreement, Defendants had no contractual duty to provide Meda with that Convention or those Amendments and, thus, they could not have been in breach for failing to do so.

3. Meda’s claim under Section 3.12 must be dismissed.

18. Meda asserts that Defendants made two misrepresentations in Section 3.12: (1) that Defendants had disclosed and made available to Meda copies of certain “Assumed Contracts” (*see* DX-281 at § 3.12(a)); and (2) that they and their Subsidiaries were not in violation or breach of any “Material Contract” (*id.* at § 3.12(b)). *See* Amended Complaint at ¶¶ 55-56. Meda’s claim is without merit.

19. Section 3.12 is inapplicable to this action because the March 2003 Convention and the 2004 and 2005 Amendments were neither “Assumed Contracts” nor “Material Contracts.” The definition of “Assumed Contracts” in Section 1.01 of the Acquisition Agreement consists of thirteen clauses, which can fairly be grouped into three categories: (1) specific contracts “that are set forth on Section 1.01(a) of the Seller Disclosure Schedule” (*i.e.*,

¹⁶ *See also* Defendants’ Memorandum of Law in Opposition to Plaintiff’s Motion *In Limine* Relating to Affirmative Defenses (#191) at 2-4.

subsections (i) - (xi)); (2) “Purchaser Shared Contracts” and certain “Nonassignable Assets;” and (3) “other contracts of the type referred to in [the foregoing clauses] entered into . . . from the date hereof to the Closing Date.” DX-281 at 3, § 1.01. “Material Contracts,” in turn, is defined as those “Assumed Contract[s] referred to in clauses (i) through (xi) of the definition thereof” that also meet one of seven materiality standards set forth in Section 3.12(a). *Id.* at 29, § 3.12(a).

20. Pursuant to the plain and unambiguous language of the Acquisition Agreement,¹⁷ the March 2003 Convention and the 2004 and 2005 Amendments were not “Assumed Contracts” because they were not listed on Section 1.01(a) of the Seller Disclosure Schedule, were not “Purchaser Shared Contracts” or “Nonassignable Assets” (as those terms are defined), and were not entered into between the date of the Acquisition Agreement and the Closing of the transaction. *See* DX-348, Seller Disclosure Schedule, at § 1.01(a) (3M00171194-232). Accordingly, they were neither “material Assumed Contracts” nor “Material Contracts.” Thus, the representations and warranties contained in Section 3.12 are inapplicable to the documents in question.

21. With respect to Meda’s allegation that Defendants breached their warranty in Section 3.12(b) regarding compliance with all Material Contracts, apart from the fact that Article

¹⁷ Far from “relying on the detailed definitions of ‘Assumed Contracts’ and ‘Material Contracts,’” Meda would have the Court consider parol evidence and/or ignore the unambiguous language of those definitions purportedly to avoid “absurd” results. *See* Meda’s COL at 8-9. Meda’s position is contrary to New York law. *See Metro. Life Ins. Co. v. RJR Nabisco, Inc.*, 906 F.2d 884, 889 (2d Cir. 1990); *Greenfield v. Philles Records, Inc.*, 98 N.Y.2d 562, 569-70 (2002). Furthermore, limiting the definition of “Assumed Contracts” (and, thus, “Material Contracts”) to those contracts “that are set forth” in specific schedules to an acquisition agreement is not only reasonable, it is absolutely necessary in order for the parties to reach agreement on the assets to be transferred. *See* DX-281 at § 2.01(a)(ii) (the “Assumed Contracts” are among the “Assets” to be conveyed); Tr. at 1506. Indeed, a CEPS convention is not transferable under any circumstances pursuant to French law (*see* Schur Trial Decl. at ¶ 86, n.21 and ¶ 94) and, thus, could not have been an “Assumed Contract.”

2.2 was not a “Material Contract,” Defendants were not in violation of Article 2.2 as of the date of the Acquisition Agreement (or at any point in time). *See supra* § A.1.

4. Meda’s claim under Section 3.15 must be dismissed.

22. Meda alleges that 3M’s alleged nondisclosure of the March 2003 Convention, the 2004 and 2005 Amendments, and 3M Santé’s letter to CEPS dated September 8, 2006 (the “September 8 Letter”) – as well as 3M Santé’s purported violation of Article 2.2 – breached the following provisions of Section 3.15:

(a) All existing material Regulatory Filings held by any Seller are set forth on Section 3.15 of the Seller Disclosure Schedule. . . . ;

(b) . . . Seller has provided Purchaser with access to true and complete copies of all Regulatory Filings and all annual and other reports submitted to Health Authorities with respect to the Products and all adverse event reports and product complaints with respect to the Products. Seller is in compliance in all material respects with all Regulatory Filings and Laws applicable to the Products, including all post-approval monitoring, reporting and other obligations; and

(d) Seller has not received any written or, to Seller’s Knowledge, other notice of proceedings from a Governmental Authority regarding any actual, alleged, possible or potential . . . (iii) renewal of the Regulatory Filings on terms less advantageous to Seller than the terms of those Regulatory Filings currently in force . . .

See Amended Complaint at ¶¶ 57-59; DX-281 at 31-32. The Acquisition Agreement defines “Regulatory Filings” as including “Marketing Authorizations,” which are:

[T]he marketing authorizations, registrations, permits and other licenses (including those now issued or pending) for a Product issued by a Health Authority that permits the clinical development, manufacture, use or sale of the Product within the Territory, and any supplements or variations thereto, including all pricing and reimbursement approvals.

DX-281 at 6, § 1.01. Meda’s claim is without merit.

23. To constitute a Marketing Authorization, a document must be issued by a “Health Authority” (*id.*), which is defined as “the Food and Drug Administration of the United States of America (‘FDA’) and/or any governmental agency in a country where Product is manufactured

or sold that is responsible for granting licenses and/or approvals permitting the clinical testing, manufacture or sale of Product in such country.” *Id.* at 5, § 1.01 (emphasis added). CEPS, which is responsible for setting the prices at which certain prescription drugs are reimbursed by the French government, has no such responsibilities. *See* Schur Trial Decl. at ¶ 27; *see also* Schur Trial Decl. at ¶ 8(a); Tr. at 540-41 (Destal); Mariotte Trial Decl. at Ex. 2, Report dated May 12, 2012, at 4, 8, and 14. Therefore, CEPS conventions and amendments thereto are not “Marketing Authorizations” (*see* Schur Trial Decl. at ¶¶ 5, 95) – a conclusion buttressed by the absence of *any* CEPS conventions (or similar pricing documents for other countries) from the contract schedules listing the Marketing Authorizations and Regulatory Filings to be transferred.¹⁸

24. In addition, the March 2003 Convention and the 2004 and 2005 Amendments did not qualify as Marketing Authorizations because they were not “supplements or variations” to any “marketing authorizations, registrations, permits [or] other licenses.” *See* Schur Trial Decl. at ¶ 95. Meda asks the Court to construe the clause “pricing and reimbursement approvals” in isolation.¹⁹ However, the Acquisition Agreement must be construed according to its plain terms, and only those “pricing and reimbursement approvals” that are “supplements or variations” to

¹⁸ *See* DX-348, Seller Disclosure Schedule, at Section 3.15(a) (3M00171391-96); DX-330, French Agreement, at Schedule 5.2(b).5 (MEDA-00071732-37). Similarly, those schedules do not list any correspondence with CEPS, such as the September 8 Letter. *Id.*

¹⁹ Meda attempts to read the word “including” near the end of the definition not as providing illustrative examples of the preceding terms, but as expanding the definition of “Marketing Authorizations” to encompass a large volume of documents that have nothing to do with the preceding terms of the definition (and which are not considered “marketing authorizations” in the pharmaceutical industry). Not only is that position contrary to the plain meaning of “including” (*see Black’s Law Dictionary*, 9th Ed., at 831, defining the word “including” as a participle that “typically indicates a partial list”), but it also conflicts with the parties’ agreed-upon definition of “including” (DX-281 at § 1.03, defining “including” as meaning “including, without limitation”).

“marketing authorizations, registrations, permits and other licenses” issued by a “Health Authority” may constitute Marketing Authorizations.²⁰ Indeed, in some jurisdictions in the 81-country “Territory,” the health agency that issues the authorization to market a product may also supplement or modify that authorization with pricing requirements²¹ – but that is not so in France.

25. Put simply, neither the CEPS convention and amendments in question, nor the September 8 Letter, were Marketing Authorizations. Accordingly, those documents were not Regulatory Filings under the Acquisition Agreement, and Meda has failed to establish any breach by Defendants of Section 3.15.

B. Meda’s Claim For Breach Of The Implied Duty Of Good Faith And Fair Dealing Is Without Merit.

26. New York law “does not recognize a separate cause of action for breach of the implied covenant of good faith and fair dealing when a breach of contract claim, based upon the same facts, is also pled.” *Harris v. Provident Life & Accident Ins. Co.*, 310 F.3d 73, 81 (2d Cir. 2002); *see also ARI & Co. v. Regent Int’l Corp.*, 273 F. Supp. 2d 518, 522 (S.D.N.Y. 2003). The implied duty serves a gap-filling purpose “in aid and furtherance of other terms of the agreement.” *See Murphy v. Am. Home Prods. Corp.*, 58 N.Y.2d 293, 304, 448 N.E.2d 86, 91 (1983). A claim for breach of that implied duty may not be used to interfere with, contradict, or

²⁰ Meda’s reliance on its modification of the definition during the drafting of the Acquisition Agreement is misplaced in light of Section 11.13 of the Acquisition Agreement, which provides: “The parties agree that this Agreement shall be deemed to have been jointly and equally drafted by them . . .” DX-281 at 62.

²¹ *See*, for example, Pharmaceutical Pricing and Reimbursement Information (PPRI) for Italy (October 2007), commissioned by the European Commission, Health and Consumer Protection Directorate-General, at 11; *see also* Pharmaceutical Health Information System (PHIS) Pharma Profile for Norway (2011) at 10. Those reports are available online through the World Health Organization (WHO).

alter the express terms and provisions of the parties' contract. *Id.*; *CIBC Bank & Trust Co. (Cayman) Ltd. v. Banco Cent. de Brasil*, 886 F. Supp. 1105, 1118 (S.D.N.Y. 1995). Yet, that is exactly what Meda seeks to do by asking the Court to infer warranties and duties of disclosure that do not appear in the Acquisition Agreement. Meda's makeweight claim for breach of the implied duty of good faith and fair dealing must be dismissed.

C. Meda's Fraud Claim Is Without Merit.

27. To establish a claim for common law fraud, Meda was required to prove: (1) a misrepresentation or a material omission of existing fact; (2) which was false and known by 3M to be false; (3) scienter, or intent to deceive; (4) Meda's reasonable reliance; and (5) damages caused by such reliance. *See Small v. Lorillard Tobacco Co.*, 94 N.Y.2d 43, 57 (1999). Meda had the burden of establishing each such element by clear and convincing evidence. *See Gaidon v. Guardian Life Ins. Co. of Am.*, 94 N.Y.2d 330, 349-50 (1999).

1. Meda failed to prove any actionable misrepresentations.

28. Meda devotes a single paragraph in its Post-Trial Conclusions of Law to the first element of its fraud claim – *i.e.*, the existence of a material misrepresentation or omission of existing fact. In addition to the representations and warranties set forth in the Acquisition Agreement – as to which, as demonstrated above, it failed to satisfy its burden – Meda bases its fraud claim on alleged extra-contractual misrepresentations and omissions, including: (i) statements regarding the profitability of its pharmaceutical business and the projections of future financial performance contained in the Offering Memorandum and Management Presentation provided to Meda; (ii) John Sampson's alleged statement at the management presentation that there was no additional information that Meda should know before moving forward; and (iii) the alleged nondisclosure of the existence of Article 2.2. *See* Meda's COL at

18. As established below, the alleged extra-contractual misrepresentations are not actionable as fraud, and there was no duty to disclose Article 2.2 of the March 2003 Convention.

a. The alleged extra-contractual misrepresentations are not actionable.

29. As demonstrated at trial (*see* Def. Fact Mem. at §§ I.A.1.b.-c. and I.B.1.), the alleged misrepresentations in the Offering Memorandum and Management Presentation regarding the projected future performance of 3M’s pharmaceutical business were non-actionable statements of opinion and good faith predictions. *See Mandarin Trading Ltd. v. Wildenstein*, 16 N.Y.3d 173, 178-79 (2011); *Cohen v. Koenig*, 25 F.3d 1168, 1172 (2d Cir. 1994); *Koagel v. Ryan Homes, Inc.*, 167 A.D.2d 822 (4th Dep’t 1990). Similarly, Mr. Sampson’s alleged statement at the management presentation that there was no additional information Meda should know would, at best, be a non-actionable opinion. *See In re Sanofi-Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 565 (S.D.N.Y. 2011) (alleged statement that “You know everything concerning [a particular drug]” was not actionable); *Century Pacific Inc. v. Hilton Hotels Corp.*, 528 F. Supp. 2d 206, 230 (S.D.N.Y. 2007) (seller’s statement that “everything’s going to be fine” was non-actionable opinion). In any event, Mr. Sampson made no such statement at the management presentation – nor would such a statement have even made sense at that early stage of the due diligence process. *See* Def. Fact Mem. at § I.A.1.d.

b. The alleged nondisclosure of Article 2.2 is not actionable.

30. To succeed on its fraud claim based on the alleged nondisclosure of Article 2.2, Meda was required to demonstrate that 3M “had a duty to disclose material information and that it failed to do so.” *See Mandarin Trading*, 16 N.Y.3d at 179. As demonstrated above, 3M had no contractual obligation to disclose Article 2.2. *See supra* § A.2.-4.

31. An “omission does not constitute fraud unless there is a fiduciary relationship between the parties.” *Cobalt Partners, L.P. v. GSC Capital Corp.*, 97 A.D.3d 35, 42-43 (1st

Dep't 2012). Meda does not contend that such a relationship exists. Instead, it tries to pigeonhole its case into the narrow exceptions to the general rule. In the absence of a fiduciary relationship, a duty to disclose may arise only if: (a) a party “possesses superior knowledge, not readily available to the other, and knows that the other is acting on the basis of mistaken knowledge;” or (b) a party makes a partial or ambiguous statement that requires additional disclosure to avoid misleading the other party. *See Remington Rand Corp. v. Amsterdam-Rotterdam Bank, N.V.*, 68 F.3d 1478, 1484 (2d Cir. 1995).

32. A “party’s knowledge is not superior where the relevant information ‘was either a matter of public record, was not pursued by plaintiffs, or was disclosed at least in part.’” *Grumman Allied Indus., Inc. v. Rohr Indus., Inc.*, 748 F.2d 729, 739 (2d Cir. 1984); *see also Jana L. v. West 129th Street Realty Corp.*, 22 A.D.3d 274, 278 (1st Dep’t 2005). Meda cannot avail itself of that exception. 3M disclosed to Meda during due diligence that price negotiations between 3M and CEPS regarding the registration renewal of Tambocor CR were ongoing, and Article 2.2 in particular was disclosed by Benoit Traineau to Meda executives at a meeting on November 28, 2006, and thereafter through the Closing on January 2, 2007. *See* Def. Fact Mem. at §§ I.A.3.c.(1) and I.C.7. Moreover, the risk of price reductions was a matter of public record. *Id.* at § I.A.3.c.(2). Meda, a sophisticated drug company with substantial experience in the French market, failed to pursue the information that it asserts was not disclosed. Despite having complete access to any information it requested, and with full knowledge of the absence of any CEPS conventions in the data room, Meda inexplicably failed to request (or even inquire about) them. *Id.* at § I.A.3.c.(3)-(4). For all these reasons, the “superior knowledge” doctrine is inapplicable.

33. In addition, 3M did not make any statements regarding the future reimbursement price of Tambocor CR in France in either the Offering Memorandum, the Management Presentation, or elsewhere that could fairly be characterized as incomplete or ambiguous. *See* Def. Fact Mem. at § I.A.3.c.(6). To the contrary, 3M expressly cautioned Meda in the Offering Memorandum that no representation or warranty was being made “as to the accuracy or completeness of the information contained” therein, and that “[t]his memorandum does not purport to contain all of the information that may be required to evaluate such transaction and any recipient hereof should conduct its own independent analysis of 3M Pharma and the data contained or referred to herein.” *See* DX-152 at i. 3M made similar disclosures in the Management Presentation. *See* DX-192 at MEDA00229916. 3M further cautioned Meda that the future performance of the pharmaceutical business was subject to risks and uncertainties regarding “pricing, reimbursement and marketing of products” that “could adversely affect the Business.” *Id.*

34. Under either the “superior knowledge” or partial statement exceptions, “a disclosure duty ripens only when it becomes apparent to the non-disclosing party that another party is operating under a mistaken perception of a material fact.” *Remington Rand*, 68 F.3d at 1484. In this case, the record is devoid of any such knowledge by 3M. Thus, 3M owed no duty of disclosure to Meda.

2. Meda has not established the requisite scienter.

35. Meda’s contention that “specific intent to defraud” is not an element of a fraud claim is wrong: “A fraud claim is not actionable without evidence that the misrepresentations were made with the intent to deceive.” *Friedman v. Anderson*, 23 A.D.3d 163, 167 (1st Dep’t 2005). As previously demonstrated (*see* Def. Fact Mem. at § I.B.), Meda failed to satisfy its burden of proving by clear and convincing evidence that any alleged misstatements and

omissions were made with scienter. To the contrary, the evidence adduced at trial demonstrates that at the time of the parties' execution of the Acquisition Agreement on November 8, 2006, and subsequent Closing on January 2, 2007, 3M did not believe that Article 2.2 was a binding obligation or was otherwise in effect. *Id.* at § I.B.2. Rather than concealing information, 3M endeavored to be open and transparent during the due diligence process. *Id.* at § I.B.4.

36. Meda's scienter argument is based almost exclusively on mischaracterizations of John Sampson's trial testimony.²² Indeed, Meda contends that "John Sampson *admitted* he committed fraud when he testified that he knowingly failed to disclose the Convention or its terms to Meda" (*see* Meda's COL at 19) when, in fact, he made no such admission. *See* Tr. at 840-46. The only evidence that Meda can muster is the fact that Mr. Sampson had knowledge of the existence of a convention and an unquantified risk of a possible reduction in the price of Tambocor CR, and that he did not disclose those facts to Meda. *See* Meda's COL at 19-22. Of course, Mr. Sampson's mere knowledge of the existence of a convention and potential for a price reduction is not proof of an "intent to deceive." *See Friedman*, 23 A.D.3d at 167. Also, absent a duty by 3M to disclose the convention to Meda, Mr. Sampson's alleged failure to so disclose was also legally irrelevant.

37. Moreover, Meda fails to acknowledge or address those portions of Mr. Sampson's testimony that demonstrate a complete *lack* of scienter on his part. For example, Mr. Sampson testified that he did not remember ever seeing the March 2003 Convention or the language of Article 2.2 (*see* Tr. at 840) and that, at most, he knew that "there was a convention that existed

²² For example, Mr. Sampson never testified that Article 2.2 posed a serious risk to 3M's pharmaceutical business. *See* Meda's COL at 3. To the contrary, he testified that "[t]heir [3M France's] judgment, given their experience, their knowledge, their connectivity, their understanding of the cardiology marketplace and their understanding of the benefits of a control release was that they stood a good chance of defending the then CR price, but there was a risk. There was a risk." Tr. at 845.

between 3M and the authorities that *may* have required 3M to change its price.” *Id.* at 841 (emphasis added). Sampson also testified that he had no knowledge of any discussions of a particular percentage price reduction (*id.*), and that “[w]hat [he] understood was that as always with this thing called convention, there is the chance that prices may be affected.” *Id.* Finally, like every other 3M fact witness, Sampson testified that he did not view conventions with CEPS as binding agreements. *See id.* at 846.

3. Meda did not reasonably rely upon any alleged extra-contractual misrepresentations or omissions by 3M.

38. Meda must show not only that it actually relied on the alleged misrepresentations and omissions, but also that such reliance was reasonable. *See Stuart Silver Assoc. v. Baco Dev. Corp.*, 245 A.D.2d 96, 98 (1st Dep’t 1997). In determining whether a plaintiff’s alleged reliance was reasonable, a court must “consider the entire context of the transaction, including factors such as its complexity and magnitude, the sophistication of the parties, and the content of any agreements between them.” *Emergent Capital Inv. Mgmt., LLC v. Stonepath Grp., Inc.*, 343 F.3d 189, 195 (2d Cir. 2003). Where, as here, “sophisticated businessmen engaged in major transactions enjoy[ed] access to critical information but fail[ed] to take advantage of that access, New York courts are particularly disinclined to entertain claims of justifiable reliance.” *Lazard Freres & Co. v. Protective Life Ins. Co.*, 108 F.3d 1531, 1541 (2d Cir. 1997) (quoting *Grumman Allied Indus.*, 748 F.2d at 737).

39. In addition, Meda was specifically informed by Benoit Traineau of the history, substance, and implications of Article 2.2 – during the management presentation on November 28, 2006, in conversations with Christian Senac (Meda France’s Country Manager) and others in December, 2006, and again within weeks of the Closing on January 2, 2007. *See* Def. Fact Mem. at §§ I.A.3.c.(1) and I.C.7. Meda presented no credible evidence controverting those

disclosures and, accordingly, can hardly claim reliance upon an alleged ignorance of facts that 3M plainly revealed to it.

40. Furthermore, in evaluating the potential acquisition of 3M's pharmaceutical business, Meda did not rely upon, or take into consideration, potential future pricing changes of *any* particular product in *any* particular country. *See* Def. Fact Mem. at § I.C.6. Thus, Meda has not proven reasonable reliance on the alleged extra-contractual misrepresentations and omissions. In any event, as demonstrated below, Meda cannot establish reasonable reliance in light of the express disclaimers to which it agreed.

a. Meda's disclaimers vitiate its assertion of "reasonable reliance."

41. "[W]here parties to an agreement have expressly allocated risks, the judiciary shall not intrude into their contractual relationship." *Grumman Allied Indus.*, 748 F.2d at 735; *see also DynCorp v. GTE Corp.*, 215 F. Supp. 2d 308, 322 (S.D.N.Y. 2002) ("it is not the role of the courts to relieve sophisticated parties from detailed, bargained-for contractual provisions that allocate risks between them"). A critical aspect of the manner in which the parties to the Acquisition Agreement allocated risk was Meda's disclaimer of reliance on all of the extra-contractual representations and omissions that form the basis of its fraud claim. *See* DX-281 at §§ 3.17 and 4.05; *see also* DX-132, Offering Memorandum, at i and 71; DX-192, Management Presentation, at MEDA00229916. A "party cannot justifiably rely on a representation that is specifically disclaimed in an agreement." *Dallas Aerospace, Inc. v. CIS Air Corp.*, 352 F.3d 775, 785 (2d Cir. 2003). Meda's "particularized disclaimers make it impossible for it to prove one of the elements of a fraud claim: that it reasonably relied on the representations that it alleges were made to induce it to enter into the [Acquisition] Agreement." *See DynCorp*, 215 F. Supp. 2d at 319-20 (citing *Danann Realty Corp. v. Harris*, 5 N.Y.2d 317, 320-21 (1959); *Harsco Corp. v. Segui*, 91 F.3d 337, 345 (2d Cir. 1996)).

42. Meda's conclusory argument that its contractual disclaimers are not sufficiently specific to be enforceable is without merit. Meda disclaimed reliance on representations made: (i) in "any projections, estimates, budgets, offering memoranda, management presentations or due diligence materials" provided or made available to Meda (*see* DX-281 at § 4.05(b)); (ii) as to "the Business (or the value or future thereof)" (*id.* at § 3.17); (iii) as to "the accuracy or completeness of any information regarding the Business that [3M] furnished or made available" to Meda (*id.*); and (iv) orally or in writing, other than those representations set forth expressly in Sections 3.01 through 3.18 of the Acquisition Agreement (*id.* at § 4.05(a)). *See DynCorp*, 215 F. Supp. 2d at 319; *Harsco Corp.*, 91 F.3d at 342. The specificity of those disclaimers is strengthened by the extensive representations and warranties contained elsewhere in the Acquisition Agreement. *See Emergent Capital*, 343 F.3d at 196; *Consol. Edison Inc. v. Northeast Utils.*, 249 F. Supp. 2d 387, 402-04 (S.D.N.Y. 2003), *rev'd in part on other grounds*, 426 F.3d 524 (2d Cir. 2005) (citing *Harsco Corp.*, 91 F.3d at 346).

43. Meda's reliance on *Bridger v. Goldsmith*, 143 N.Y. 424 (1894), and *Jackson v. State*, 205 N.Y.S. 658 (4th Dep't 1924), *aff'd*, 241 N.Y.2d 563 (1925), for the erroneous proposition that "a party may not immunize itself from fraud with disclaimers" is misplaced. *See* Meda's COL at 26. As reflected in the Court of Appeals' decision in *Danann Realty Corp.* – the seminal New York case on the enforcement of disclaimers of reliance – *Bridger* and *Jackson* are inapplicable to this action. *See Danann*, 5 N.Y.2d at 321 ("[T]his clause, which declares that the parties to the agreement do not rely on specific representations not embodied in the contract, excludes this case from the scope of the *Jackson* . . . [and] *Bridger* . . . cases."). Meda's reliance on *Sabo v. Delman*, 3 N.Y.2d 155 (1957), which concerned a general merger clause, as opposed to specific disclaimers of reliance, is similarly misplaced. *See Danann*, 5 N.Y.2d at 321.

b. The “peculiar knowledge” doctrine is inapplicable.

44. In light of Meda’s specific disclaimers, Meda is forced to rely on an exception to the general rule that such disclaimers vitiate claims of reasonable reliance – namely, the “peculiar knowledge” exception. That exception “is designed to address circumstances where a party would face high costs in determining the truth or falsity of an oral representation, and those costs are sufficiently great to render reliance upon the representation reasonable.” *Warner Theatre Assocs. L. P. v. Metro. Life Ins. Co.*, 149 F.3d 134, 136 (2d Cir. 1998). It is based on the premise that when “matters are . . . peculiarly within the defendant’s knowledge . . . plaintiff may rely without prosecuting an investigation, as he has no means of ascertaining the truth.” *Dimon Inc. v. Folium, Inc.*, 48 F. Supp. 2d 359, 368 (S.D.N.Y. 1999).

45. However, “if the plaintiff has the *means* of learning the facts and disclaims reliance on the defendant’s representations, there is simply no reason to relieve it of the consequences of both its failure to protect itself and its bargain to absolve the defendant of responsibility.” *Dimon Inc.*, 48 F. Supp. 2d at 368 (emphasis added). Factors relevant in determining whether a party may avail itself of the “peculiar knowledge” exception are the buyer’s level of sophistication and access to the information underlying the alleged misrepresentation. *Id.* In general, the “more sophisticated the buyer, the less accessible must be the information to be considered within the seller’s peculiar knowledge.” *Id.* at 369 n.55.

46. Meda has failed to prove that the allegedly misrepresented facts were “peculiarly” within 3M’s knowledge such that Meda should not be held to its specific disclaimers of reliance. Meda admitted in the Acquisition Agreement that it “is experienced and sophisticated with respect to the transactions contemplated” and, in conducting its independent evaluation of the 3M’s pharmaceutical business, had “full and complete access” to the documents that it asked to review. *See* DX-281 at §§ 4.05(a) and 3.17; *see also Lazard Freres*, 108 F.3d at 1543. Although

Meda was fully aware of the absence in the data room of *any* French CEPS conventions and reimbursement pricing agreements from other countries, it did not request or even inquire about them. *See* Def. Fact Mem. at § I.A.3.c.(3) and (4).

47. In sum, Meda cannot establish reasonable reliance on the alleged misrepresentations and omissions concerning information it knew or would have known had it made use of the means of verification that were available to it. *See Venture Group, LLC v. Finnerty*, 68 A.D.3d 638, 639 (1st Dep’t 2009); *First Nat’l State Bank v. Irving Trust Co.*, 91 A.D.2d 543, 544 (1st Dep’t 1982). Accordingly, 3M is entitled to judgment on Meda’s fraud claim.

D. Meda Sustained No Legal Injury And Is Entitled To No Damages.

1. Meda’s damages model is not based on any objective standard.

48. The measure of fraud damages arising out of the sale of a business is the “difference between the actual purchase price of the business and its true value as of the date of the sale, plus interest.” *See Merrill Lynch & Co., Inc. v. Allegheny Energy, Inc.*, 500 F.3d 171, 183 (2d Cir. 2007). With respect to a claim for breach of warranty, the measure of damages is “the difference between the value of [the business] as warranted [by seller] and its true value at the time of the transaction.” *Id.* at 185. Where the objective is to value a business at a single point in time, the preferred methodology is discounted cash flow. *See Sharma v. Skaarup Ship Mgmt. Corp.*, 916 F.2d 820, 826 (2d Cir. 1990); *Lippe v. Bairnco Corp.*, 288 B.R. 678, 689 (S.D.N.Y. 2003); *In re Diversified, Inc.*, 334 B.R. 89, 99 (Bankr. E.D.N.Y. 2005); *In re CNB Int’l, Inc.*, 393 B.R. 306, 323-24 (Bankr. W.D.N.Y. 2008). However, Meda failed to offer *any* evidence of the “true value” of the pharmaceutical business in question and, thus, failed to produce the requisite evidence to establish “the fact of damages or the means of calculation of same.” *See Lewin v. Lipper Convertibles, L.P.*, 756 F. Supp. 2d 432, 440-45 (S.D.N.Y. 2010).

Instead, Meda submitted only the subjective testimony of its executives – benefitted by hindsight and motivated by a desire to obtain hundreds of millions of dollars – that they would have sought a purchase price reduction had they known of the facts allegedly withheld from them. Meda’s theory is based on two allegations: (1) the total price that it agreed to pay for the pharmaceutical business in question was determined by applying a multiple to projected 2007 EBITDA (*see* Lonner Trial Decl. at ¶ 84; Larnholt Trial Decl. at ¶¶ 57 and 68; Stenqvist Trial Decl. at ¶ 42); and (2) had it known of the purported continuing existence of Article 2.2 and the presumed requirement therein to reduce the price of Tambocor CR, Meda would have either refrained from entering into the transaction or, alternatively, requested a lower purchase price (*see* Lonner Trial Decl. at ¶¶ 68 and 84; Larnholt Trial Decl. at ¶¶ 103 and 106-08; Stenqvist Trial Decl. at ¶ 81). Such a subjective, after-the-fact assessment is insufficient to support a claim for causation or damages under New York law. *See Continental Cas. Co. v. PricewaterhouseCoopers, LLP*, 15 N.Y.3d 264, 271 (2010).

2. Article 2.2 merely reflected ministerial guidelines and, thus, would not have caused a reasonable purchaser to pay a lower price.

49. Article 2.2 essentially encapsulated CEPS pricing policies for counter-generic drugs such as Tambocor CR. *See* Schur Trial Decl. at ¶¶ 5, 36, 45, 49, 67, 74, 81, and 96. One of the principal mandates of CEPS is to “give effect to the guidelines that it receives from the competent ministers.” DX-56, Art. R 162-17-3, at 5 of 8. Those guidelines are a “means for ensuring adherence to the national target on health insurance expenditure,” and CEPS “applies these guidelines to the fixing of the prices of medications, which it carries out in accordance with article L 162-17-4.” DX-37 (2004 *Servier* decision), at 7 of 9.

50. Tambocor CR, which is the controlled-release version of flecainide acetate, is an ASMR IV pharmaceutical product (*see* Schur Trial Decl. at ¶¶ 12-14, 38, and 76) that has the

same active pharmaceutical ingredient and is used for the same indication (arrhythmia) as Tambocor IR, the immediate-release version of the drug. *See* JX-49 at MEDA 177765, 177788, and 177790. Tambocor CR was introduced to “counter generic competition” to Tambocor IR. *See* DX-167 at 10. Therefore, pursuant to CEPS’ policies, Tambocor CR is a counter-generic drug. *See* DX-412 at 20; Schur Trial Decl. at ¶¶ 24, 32, 35, and 76. One of the controlling ministry guidelines and CEPS policies throughout the relevant period was to set the price of ASMR IV counter-generic drugs in such a way as not to impose any additional cost to the French health care system relative to the price of the proprietary drug that the counter-generic was intended to replace.²³ Another prevailing CEPS policy in 2006 was to reduce the price of pharmaceutical products, especially proprietary drugs facing generic competition (such as Tambocor IR). *See* PX-417A at 15; DX-38 at 45; DX-38 at 15. In fact, to no one’s great surprise, reference pricing (TFR) was imposed upon Tambocor IR in 2007, resulting in a 37% price decrease. *See* Maupas Dep. at 77-78; Schur Trial Decl. at Ex. 4 and at ¶¶ 59-60, 64, and 68. The combination of the foregoing policies meant that CEPS would ultimately seek to align the price of Tambocor CR with the price of the generic competitors of Tambocor IR. *See* Schur Trial Decl. at ¶ 77; DX-412 at 21. Together, those policies exposed Tambocor CR to a potential price decrease of 40-50%. In sum, Article 2.2 contributed no knowledge in addition to, or different from, the publicly-available pricing policies of CEPS. *See* Tr. at 1362-63 (Schur);

²³ As of February 24, 2006, the price of 100mg (30 pills) of Tambocor IR was 43% less than the price of 100 mg (30 pills) of Tambocor CR. Measured by the daily treatment cost (“CTJ”), the price of the same quantity of Tambocor IR was approximately 15% less than that of Tambocor CR. *See* Schur Trial Decl. at Ex. 4. Thus, under the circumstances existing in 2006, that ministerial guideline and CEPS policy called for a substantial future price decrease for Tambocor CR. *See* DX-38 at 28-29; *id.* at 44-45; PX-417A at 43; DX-195 at 25 of 28; Schur Trial Decl. at ¶¶ 32, 34, and 73.

Schur Trial Decl. at ¶¶ 15-17, 31, 38, 63, 74, 77-79, and 81-82.²⁴ Thus, no reasonable purchaser of the French Business and Assets would have paid less by knowing of Article 2.2.

3. Because Article 2.2 ceased to exist prior to the Acquisition Agreement, it could not have affected the pricing decisions of a reasonable purchaser.

51. As demonstrated above, Article 2.2 *did not exist* as of the parties' execution of the Acquisition Agreement on November 8, 2006, or the subsequent Closing on January 2, 2007. In addition, prior to its elimination, Article 2.2 *did not require* a reduction in the price of Tambocor CR – by 50% or otherwise. The operative Convention Amendment, dated September 15, 2006, provided for an indefinite continuation of the €17.10 price of Tambocor CR – which had been the prevailing price since it was first introduced to the French pharmaceutical market in 2003. *See* JX-95 and JX-95A. Thus, the 2007 projections of 3M Sante and Meda France were not subject to change as a result of Article 2.2.

4. In any event, 3M Santé informed Meda about Article 2.2 prior to the Closing, and Meda nevertheless decided to proceed with the acquisition.

52. The information that Meda asserts it lacked was, in fact, disclosed by 3M prior to the Closing. *See* Def. Fact Mem. at § 1.A.3.c.(1). *See also supra* § C.3. Rather than declaring a “Material Adverse Effect” or otherwise refusing to move forward once it had knowledge of the prior-existing Article 2.2, Meda proceeded with the purchase. *See* Def. Fact Mem. at § I.C.7. Having been informed by 3M Santé of the facts regarding Article 2.2, Meda is not entitled to fraud or breach of warranty damages. *See Merrill Lynch*, 500 F.3d at 182 and 186.

²⁴ Fortunately for Meda, the actual reductions in the price of Tambocor CR have not been as severe to date as would otherwise have been required by strict application of CEPS' pricing policies. *See* Schur Trial Decl. at Ex. 4 and ¶¶ 6, 66, and 71. *See also* Mariotte Trial Decl. at Ex. 4, Rebuttal Report dated July 6, 2012, at 14 (“Flecaine LP still enjoys a higher reimbursement price than Flecaine LI to this day, in violation of the CEPS' policy.”).

5. The opinions of Meda's damages experts are unreliable.

53. The damages case constructed by Meda's trinity of experts (Neuberger, Gallagher, and Mariotte) does not meet the applicable standards of reliability. *See* Defendants' Memorandum in Support of Motion to Preclude Expert Testimony (#60); Defendants' Reply (#116); *Rink v. Cheminova*, 400 F.3d 1286, 1294 (11th Cir. 2005). Neuberger's damages figures rely on inputs from Gallagher and Mariotte (*see* Def. Fact Mem. at § I.D.1); however: (a) Gallagher rendered a series of demonstrably-incorrect EBITDA calculations based on assumptions provided by Meda's counsel; and (b) Mariotte offered subjective speculations regarding the odds of CEPS enforcing Article 2.2 based on the false assumptions that Article 2.2 continued to exist as of the date of the transaction and required a 50% reduction in the price of Tambacor CR. *Id.* Left without a credible case for any specific damages figure, Meda is relegated to the fallback argument that Neuberger's "plug-and-play" formula theoretically allows the Court to divine its own amount. *See* Tr. at 794 and 808-10 (Neuberger).

6. Meda sustained no injury as a result of the transaction.

54. Meda suffered no out-of-pocket loss in connection with the purchase of the French Business and Assets, including the marketing authorizations and contracts relating to Tambacor CR. *See* Def. Fact Mem. at § I.D.2. Rather, Meda obtained a valuable receivable from Meda France in consideration of a loan it extended to that Subsidiary for the purchase and acquisition of that property. *Id.* There is no evidence that Meda's rights with respect to that receivable have been impaired in any way. Put simply, Meda functioned as a lender – and not as a buyer – with regard to the French transaction, and there is no proof of any injury sustained in that capacity. The Court should therefore deny Meda's request for an award of damages.

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Respectfully submitted,

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